

MAR 15 2012

K112404

## **510(k) SUMMARY**

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### **General Information**

Trade Name	Concentric Balloon Guide Catheter
Common Name	Percutaneous Catheter
Classification	Percutaneous Catheter, 21CFR 870.1250 – Class II
Owner	Concentric® Medical, Inc. 301 E. Evelyn Avenue Mountain View, CA 94041 Tel 650-938-2100 Fax 650-938-2700
Contact	Kirsten Valley Senior Vice President, Technology and Regulatory Affairs
Date Prepared	August 4, 2011

### **Predicate Device**

Concentric Balloon Guide Catheters (K102657)

### **Device Description**

The Concentric Balloon Guide Catheters are coaxial-lumen, braid-reinforced, variable stiffness catheters designed for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. A radiopaque marker is included on the distal end for angiographic visualization. A compliant balloon is mounted on the distal end to provide temporary vascular occlusion during angiographic procedures. A bifurcated luer hub on the proximal end allows attachments for flushing, inflation and aspiration. Balloon Guide Catheter dimensions and maximum recommended balloon inflation volume are indicated on product label. If indicated on product label, a dilator is provided.

### **Indications for Use**

The modified Indications for Use are as follows:

The Concentric Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.

The modification to the indications does not impact the intended therapeutic use of the device. As a result, the safety and effectiveness of the device are not impacted when used as indicated.

### **Technological Characteristics**

The Concentric Balloon Guide Catheter has the same technological characteristics as the predicate device. A colorant has been added to the dilator. Apart from this minor modification, the device design, materials used, function, physical properties and composition have not been changed.

### **Testing Summary**

The same performance standards and specifications as those previously submitted in the predicate device 510(k) submission are applicable. No additional verification or validation testing was required for

the change to the indications statement requested in this submission. The results of verification and validation conducted on the predicate device remain applicable. Specifically, the device meets the pre-determined specifications for the following tests:

- Tensile Testing
- Leak Testing
- Dimensional Testing
- Torque Testing
- Kink Resistance
- Simulated Use
- Biocompatibility Testing
- Balloon Fatigue
- Inflation/Deflation Testing

To confirm the biocompatibility of the new colorant, the following testing was successfully performed:

- Hemolysis, Direct Contact Method
- Hemolysis, Extract Method
- Cytotoxicity – ISO MEM Elution

Based on conformance with these test requirements, the Concentric Balloon Guide Catheter is as safe and effective as the legally marketed predicate device.

#### **Summary of Substantial Equivalence**

The Concentric Balloon Guide Catheters are substantially equivalent to the predicate device with regard to device design, intended use, and patient population.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Concentric Medical, Inc.  
c/o Regulatory Technology Services, LLC  
Mr. Mark Job  
Responsible Third Party Official  
1394 25<sup>th</sup> Street NW  
Buffalo, MN 55313

MAR 15 2012

Re: K112404  
Trade/Device Name: Concentric Balloon Guide Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: DQY  
Dated: February 28, 2012  
Received: February 29, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**

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**INDICATIONS FOR USE**

510(k) Number (if known):

K112404

Device Name:

Concentric Balloon Guide Catheter

Indications for Use:

The Concentric Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neurovascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.

Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Amy N. Hoang  
(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

510(k) Number K112404